REMARKS

I. Status of the Claims

Claims 1-5 and 8-10 are pending and under consideration. Applicants are pleased to note that the Office has withdrawn all previous rejections and objections set forth in the August 11, 2004, Office Action. The Office, however, has cited a new reference as anticipating amended claims 1 and 2. Claims 3-5 and 8-10 are objected to as being dependent upon a rejected base claim, but the Office states these claims would be allowable if rewritten in independent form including all the limitations of the base and any intervening claim. Final Office Action, page 3.

Claim 9 is, and always has been, an independent claim. Claim 10 depends from claim 9. Claims 9 and 10 are not included in the new grounds of rejection set forth in the November 3, 2004, Final Office Action, and do not appear to be objected to on any other grounds. Applicants therefore respectfully request the Office indicate that claims 9 and 10 are allowable on the next PTOL-326.

II. Finality of the November 3, 2004, Office Action

The Office made the November 3, 2004, Office Action final, stating that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action." Final Office Action, page 4. Applicants respectfully disagree with the Office's decision to make this Office Action Final. Although claims 1 and 2 were amended, this amendment limited the claims to the elected Type VI collagen and decorin. Nothing about this amendment "necessitated" the new ground of rejection because the Office had previously examined the claims in view of this election.

Applicants provide reasons below why the newly applied reference does not anticipate claims 1 and 2 so that the application may be passed to issue. If, however, the Office decides to maintain this ground of rejection, then Applicants respectfully submit that the Office should withdraw the finality of the November 3, 2004, Final Office Action.

III. Rejection of claims 1 and 2 under 35 U.S.C. § 102(e)

The Office now rejects claims 1 and 2 under 35 U.S.C. § 102(e) as being anticipated by Cintron et al. (U.S. Patent No. 6,218,360) ("*Cintron*"). Final Office Action, page 2. *Cintron* is cited as teaching in Example 11 a "method of maintaining a desired shape of cornea" by administering a composition comprising Type VI collagen. *Id.* at 3.

The Office's rejection rests on the characterization of the procedures described in Example 11 as "orthokeratological." Final Office Action, page 3. Example 11 of *Cintron*, however, is a surgical procedure and does not involve the application of contact lenses. The specification on page 2 states that an orthokeratological procedure is a *non-surgical* procedure. In addition, the procedure utilizes contact lenses to reshape the cornea. *Id.* The patient of claim 1 is a patient that has undergone an orthokeratological procedure, as recited in the preamble. In claim 1 the preamble breathes life and meaning into the claim since the administered composition acts to stabilize the shape of the cornea achieved via the orthokeratological procedure.

A rejection under 35 U.S.C. § 102 is only proper when the claimed subject matter is identically described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *see also* M.P.E.P. § 706.02(a) ("For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or

impliedly."). Each and every element of a claim must be set forth in the prior art reference for there to be anticipation. *See* M.P.E.P. § 2131.

Here, *Cintron* does not teach all the claimed limitations because the patient in *Cintron* has not had "an orthokeratological procedure," as required by claim 1. Consequently, *Cintron*'s surgical procedure using a plug of a composition that includes Type VI collagen does not anticipate the claimed method for maintaining a desired shape of corneal tissues following an orthokeratological procedure. The teaching of *Cintron* regarding the application of the gelsix or crosslinked cxgelsix to wounds or scars following ophthalmic surgery does not anticipate the instant method for the same reasons. In addition, although *Cintron* at column 14, lines 27-35, does mention a reshaped cornea, this reshaping occurs *after* the application of the cxgelsix sheet to the incised cornea. In contrast, the instant method requires the application of the composition to stabilize the corneal tissues and maintain the desired shape that has already been achieved via the orthokeratological procedure *before* the composition is applied.

The methods of *Cintron* and instant claims 1 and 2, therefore, involve different steps. Accordingly, even though both methods result in a reshaped cornea, the surgical method of *Cintron* is clearly different from the instantly claimed method. This difference in method steps would be readily appreciated by any patient faced with choosing between a procedure that cuts the cornea (*Cintron*'s method) and a procedure that requires the wearing of contact lenses (the orthokeratological procedure of the claimed method). Because the claimed method is not identically described or disclosed in

Cintron, the rejection of claims 1 and 2 under 35 U.S.C. § 102 is improper and should be withdrawn.

CONCLUSION

In view of these remarks, Applicants submit that this application is in condition for allowance. An early and favorable action is earnestly solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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